DETAILED ACTION

Notice of Amendment

In response to the amendment filed on 6/16/2011, amended claims 1, 5, 7, 10, 13, 15, 25, and 26 and cancelled claims 18-24 are acknowledged. Claims 1-17, 25, and 26 are pending. The following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the first end face" in line 4. There is insufficient antecedent basis for this limitation in the claim. The Examiner notes that there is antecedent basis for “the first end” but not "the first end face".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-8, 10, 12-16, 25, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al. (US Patent No. 5,855,801).

Regarding claim 1, Lin et al. discloses an in vivo diagnostic or therapy micro-device (10, 120) comprising:

a substantially longitudinal body (14) having a quadrilateral-shaped section, provided with at least one main canal (78, 122, 124) in the direction of its length, one input (22) of which is located at a first end of the body, wherein the first end face is a proximal face (see Figures 1A, 8A, and 8B and col. 3, lines 34-36), and

a plurality of secondary canals (126) connected to at least one main canal and opening up sideways by lateral outputs (see Figures 8A and 8B and col. 10, lines 16-29),

wherein the in vivo diagnostic or therapy micro-device is implantable (see col. 3, lines 31-34 and col. 9, lines 48-64).

Regarding claim 2, Lin et al. discloses one or more electrodes (84) located on an outside portion of the body,

one or more electrical connection pins (36) located at the first end of the body, close to the input to said canal (see Figures 1A, 2A, 8A, and 8B and col. 3, lines 59-63).

Regarding claim 10, Lin et al. discloses an in vivo diagnostic or therapy micro-device (10, 120) comprising:

a substantially longitudinal body (14) having a quadrilateral-shaped section, provided with at least one main canal (78, 122, 124) in the direction of its length, one input (22) of which is located at a first end face of the body, wherein the first end face is a proximal face (see Figures 1A, 8A, and 8B and col. 3, lines 34-36),

one or more electrodes (84) located on an outside portion of the body; and

one or more electrical connection pins (36) located at the first end face of the body, close to the input to said canal (see Figures 1A, 2A, 8A, and 8B and col. 3, lines 59-63),

wherein the in vivo diagnostic or therapy micro-device is implantable (see col. 3, lines 31-34 and col. 9, lines 48-64).

Regarding claims 4 and 12, Lin et al. discloses at least two parallel main canals (122,124; and see Figures 8A and 8B).

Regarding claims 5 and 13, Lin et al. discloses at least one of the main canals opening up to a second end (18) of the body, wherein the second end is a distal face, and the input into the at least one main canal being funnel-shaped (see Figure 1 and col. 4, lines 25-30).

Regarding claims 6 and 14, Lin et al. discloses the body having two parallel opposite surface areas between the first and the second ends, and comprising a second bevel-shaped end (18, 86; and see Figure 1 and col. 4, lines 25-30).

Regarding claims 7 and 15, Lin et al. discloses the body having a square or rectangular section (14) in which each side has a maximum dimension of less than 900 μm, and the longitudinal extension of the body being preferably between 0.5 cm and 3 cm (see col. 3, lines 53-57 and col. 4, lines 10-30).

Regarding claims 8 and 16, Lin et al. discloses the device being made of silicon (46; and see col. 4, lines 30-35).

Regarding claims 25 and 26, Lin et al. discloses the maximum dimension is less than 300 μm (see col. 3, lines 53-57 and col. 4, lines 10-30).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. (US Patent No. 5,855,801).

Regarding claims 3 and 11, Lin et al. discloses the electrical connection pins (36) comprising micro-cavities made in the body of the micro-device (see Figures 1A-C). Further, Lin et al. discloses micro-device dimensions on the same scale (μm) as Applicant's claimed invention (see col. 3, lines 53-58). Although Lin et al. does not specifically teach cavities having a height and width between 10 μm and 50 μm, the claim would have been obvious because a person of ordinary skill at the time of the invention would have a good reason to pursue the known options within his or her technical grasp (i.e. etching a cavity with a height and width between 10 μm and 50 μm). If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense. Thus, it would have been obvious to a person of ordinary skill in the art at the time of the invention to etch the cavities of Lin et al. to have a height and width between 10 μm and 50 μm, as a person with ordinary skill has a good reason to pursue the known options within his or her technical grasp. In turn, because the micro-device as claimed has the properties predicted by the prior art, it would have been obvious to make a micro-device having the specific cavity height and width between 10 μm and 50 μm.

Claims 9 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. (US Patent No. 5,855,801) in view of Johnck et al. (US Publication No. 2003/0161572 A1).

Regarding claims 9 and 17, it is noted that Lin et al. does not specifically teach a micro-device further comprising a wave-guide. However, Johnck et al. discloses a micro-device further comprising a wave-guide (see [0009], [0028], and [0033]). It would

have been obvious to one of ordinary skill in the art at the time of invention to modify the micro-device of Lin et al. to include a wave-guide, as disclosed in Johnck et al., so as to allow the micro-device to be used in absorption and fluorescence measurements (see Johnck et al.: [0007] and [0034]).

Response to Arguments

Applicant's arguments filed 6/16/2011 have been fully considered but they are not persuasive.

Applicant argues the rejection of the claims as being anticipated by Lin et al., specifically arguing with respect to claims 1 and 10:

- Lin et al. does not disclose or suggest an implantable micro-device with fluidic and electrical connections in the face of the body
- One of ordinary skill in the art would not combine the Johnck et al. device, which is not implantable, with Lin et al. to arrive at the presently claimed device which is implantable

The Examiner disagrees, maintains the rejection as set forth and cited above, and in response notes the following:

In response to Applicant's arguments that Lin et al. does not disclose or suggest an implantable micro-device with fluidic and electrical connections in the face of the body, the Examiner firstly notes that the device is implantable in that Lin et al. explicitly discloses implantation into tissue, a blood vessel, or a small tumor to analyze blood or administer drugs (see col. 3, lines 31-34 and col. 9, lines 48-64). The device of Lin et al. includes fluid port 22 (i.e. input), which is "located on shank or proximal end 12 of shaft

14" (see col. 3, lines 34-36). Similarly, contact pads 36 (i.e. electrical connection pins) are located at the same proximal end 12, surrounding the input 22 (see Figures 1A, 2A, 8A, and 8B). It appears Applicant has applied a particularly limited interpretation of the claimed "first end face" or "proximal face". The Examiner notes that under the broadest reasonable interpretation, the top surface (i.e. face) of the interface region 11 of the device of Lin et al., which includes both input 22 and electrical connection pins 36 in/on its surface, meets Applicant's claimed "first end face" or "proximal face". Further, the Examiner notes that the claim language merely requires one input/one or more electrical connection pins "located at a first end face of the body", and not fluidic and electrical connections located in the face of the body as argued. "Located at" fairly and reasonably suggests a nearby relationship between the input/electrical connection pins and the first end face, whereas "located in" requires that the input/electrical connection pins be formed directly in/on the surface of the first end face.

In response to applicant's argument that one of ordinary skill in the art would not combine the Johnck et al. device, which is not implantable, with Lin et al. to arrive at the presently claimed device which is implantable, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Johnck et al. is relied upon only to teach a wave guide which is lacking from the implantable Lin et al. device. Both Johnck

et al. and Lin et al. teach micro-devices, and Johnck et al. is completely silent as to whether or not the device can be implanted. One of ordinary skill in the art would be motivated to include a wave guide, such as that taught by Johnck et al., in the implantable micro-device of Lin et al. in order to take absorption or fluorescence measurements of the fluid in the canal of the device (see Johnck et al.: [0007] and [0034]). For example, when the Lin et al. micro-device is used as a real-time blood analysis system (see col. 9, lines 48-55), it would be particularly useful to include the wave guide of Johnck et al. to quantitatively measure the absorption and/or fluorescence of the blood to detect concentrations of analytes and other blood components.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEVIN HENSON whose telephone number is (571)270-5340. The examiner can normally be reached on M-F 6:30-3.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. H./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736